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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,443	11/16/2001	Hyam I. Levitsky	213026	1421

8968 7590 05/03/2004

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/992,443	LEVITSKY ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-14,17-28,40-47 and 50-53*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

JANICE LI
PATENT EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because:
WRITTEN DESCRIPTION REQUIREMENT
Claims 1-14, 17-28, 40-47, and 50-53 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record and below.
With respect to the term "naturally", applicants argue that the specification does not redefine the term contrary to its ordinary meaning, and the Examiner understands the meaning of the claims.
In response, the Examiner understands the arguments presented by the Applicants, but disagrees with the definition because given its ordinary meaning, one would not generally consider that the loss of MHC expression as a result of a cancerous mutation as "naturally". The question was raised in this provision because the only well known cells that are not mutated and naturally lack both MHC-I & II would be red blood cells, but there are no known cell line for RBC on record. This is important because it indicates that the specification fails to disclose any non-mutated cell line that naturally lacks both MHC-I & II, which should be part of the invention. Even though applicants can call cells with cancerous mutation as "naturally", the specification fails to provide an adequate written description for a species and the GENUS of cell lines that lacking both MHC-I & II and HEALTHY, i.e. not mutated, which is encompassed by the claims.
Applicants then allege that the rejection to the term is the only and hence ill-founded basis for a rejection for lack of written description. The cell lines naturally lacking both MHC-I & II could be readily determined, again citing art of record as support.
In response, the Office has indicated in the final Office action (mailed 12/17/03) that the key issue or the sole basis for this rejection is that the specification fails to show at the time the application was filed, applicants were in possession of the claimed GENUS of the universal bystander human cell lines (pages 3-6). Klein et al, Wang et al, Ferrone et al, and Winchester et al teach the presence of numerous cancerous cell lines, they only provide probability that such cell line MAY exist. However, other than K562.(check), they do not disclose nor the specification teaches, a single cell line that is known of lacking both MHC-I & II. This is where the case law comes in, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Since neither the instant disclosure nor the prior art of record teaches a cell line other than K562 that meets claim limitation, the following case law applies. The court states, "IN CHEMICAL CASE WHERE APPLICANT DISCLOSES THAT ONE SPECIES OF A CLASS OF CHEMICALS WILL ACCOMPLISH CERTAIN PURPOSE WITHOUT NAMING ANY OTHERS OF CLASS TO WHICH IT BELONGS OR WITHOUT SO DESCRIBING THE SPECIES AND ITS MODE OF OPERATION AS TO CALL ATTENTION TO FACT THAT OTHER MEMBERS OF CLASS ARE ITS EQUIVALENTS AND WILL PERFORM SAME FUNCTIONS, HE IS NOT ENTITILED TO BROADER SCOPE OF DISCLOSED INVENTION BY CLAIMING WHOLE GROUP EVEN THOUGH THOSE SKILLED IN ART MAY KNOW THAT IN SOME RESPECTS AT LEAST DIFFERENT MEMBERS OF GROUP ARE EQUIVALENTS; CERTAIN MEMBERS OF WELL-DEFINED GROUP OF CHEMICALS MAY BE EQUIVALENTS FOR ONE PURPOSE AND NOT EQUIVALENT FOR ANOTHER. (In re Soll, 97 F.2d623, 38 USPQ 189 (CCPA 1938). Therefore, for reasons of record and those set forth above, the instant specification fails to meet the written description requirement set forth under 35 U.S.C. §112, 1st paragraph.

For reasons of record and set forth above, the proposed amendment of claim 1 would obviate the rejection under 35 U.S.C. § 112, second paragraph, but not the rejection under this provision.

ENABLEMENT REQUIREMENT
Claims 1-14, 17-28, 40-47, and 50-53 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record and below.
Applicants argue that the cell lines naturally lacking both MHC-I & II could be readily determined, thus, no undue experimentation is required.
However, as indicated in the written description section, the claims encompass any cell line in the universe, yet so far K562 is the only cell line known in the art that meets claim limitation. Accordingly the genus is largely unknown and the specification fails to describe such, it would require undue experimentation to unearth the claimed genus. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. It requires experimentation for the skilled to search for the genus of cell lines that meet claim limitation.
Applicants then allege that the Office contradicting itself in interpreting the Ferrone et al reference under this provision and in Obviousness rejection.
In response, it is noted that the provisions of 35 U.S. C. § 112 and 103 evaluates different aspects of a claim. Ferrone reference teaches only the probabilities of melanoma cells, whereas the claims encompass any type of cells, mutated or not, the specification fails to meet the provision under § 112. On the other hand, Ferrone reference is relied upon under § 103 because it teaches that certain melanoma cells do lack MHC-I, here, the intrinsic property was relied upon.
With respect to the defined medium, the specification fails to teach applicants define the medium as any culture medium lacking a serum and submitted formula datasheet for commonly used basic culture media such as MEM and Ham's F-12. However, the claims encompass, and the illustrated embodiment is melanoma cells, and the art of record teaches that growing melanoma cells require the presence of an animal serum (Winchester et al, right column, page 6235). In view of such, the claims do not appear to be enabled in the absence of evidence to the contrary.
Accordingly, for reasons of record and those set forth above, the instant specification fails to meet the statutory enablement requirement set forth under 35 U.S.C. §112, 1st paragraph.

Claims 1-14, 17-22, 26, 27, 40-47, and 50-53 stand rejected under 35 U.S.C. 112, second paragraph, for reasons of record and below.
With respect to the term "naturally", applicants argue that the specification does not redefine the term contrary to its ordinary meaning, and the Examiner understands the meaning of the claims.
In response, the Examiner understands the arguments presented by the Applicants, but disagrees with the definition because given its ordinary meaning, one would not generally consider that the loss of MHC expression as a result of a cancerous mutation as "naturally".

Claims 1, 5, 7, 17, 20, 22, 28, 40, 41, 44, 45, 50, and 52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dranoff et al (US 5,637,483, IDS/AB), in view of Ferrone et al (Immunol Today 1995;16:487-94), and as evidenced by Thomas et al (Human Gene Ther 1998 Apr;9:835-43).

Applicants allege that the Office fails to appreciate that there is no teaching in Ferrone et al to modify the teachings of Dranoff et al, and the Examiner fails to point to any motivation to combine reference.
In response, Dranoff et al already modified melanoma cells with a nucleic acid encoding GM-CSF, thus, not only the motivation of making and using such cells has been suggested, the cells and methods have been carried out in the art as well. Thomas et al has evidenced that some of these melanomas may intrinsically lack MHC-Class I. Ferrone et al not only confirm the evidence provided by Thomas et al but also teach what it means to cancer therapy knowing the fact that some of the melanomas lacking MHC-I expression. Ferrone et al provides clear suggestion to use such knowledge for the benefit of cancer therapy. Accordingly, the rejection stands.

Claims 1, 5, 7, 11, 17, 20, 22-24, 28, 40, 41, 44, 45, 50, and 52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dranoff et al (US 5,637,483, IDS/AB), and Ferrone et al (Immunol Today 1995;16:487-94) as applied to claims 1, 5, 7, 17, 20, 22, 28, 40, 41, 44, 45, 50, and 52 above, and further in view of Shepard et al (US 6,348,352) or Polack et al (US 6,521,449) for reasons of record and set forth in the immediate preceding paragraph.

Claims 1-14, 17-28, 40-47, and 50-53 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,973, for reasons of record.